

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[UNDER SEAL],

Plaintiffs,

vs.

[UNDER SEAL],

Defendant.

) Case No.

) COMPLAINT

) FILED IN CAMERA AND UNDER SEAL
) PURSUANT TO 31 U.S.C. §3730(b)(2)

MJG 10 CV 1601

DOCUMENT TO BE KEPT UNDER SEAL

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AT BALTIMORE
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DISTRICT OF MARYLAND

BY

DEPUTY

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, and the)	Case No.
STATES OF CALIFORNIA, DELAWARE,)	
FLORIDA, GEORGIA, HAWAII, ILLINOIS,)	COMPLAINT FOR VIOLATION OF
INDIANA, LOUISIANA,)	FEDERAL FALSE CLAIMS ACT [31 U.S.C.
MASSACHUSETTS, MICHIGAN,)	§3729 <u>et seq.</u>]; CALIFORNIA FALSE
MONTANA, NEVADA, NEW HAMPSHIRE,)	CLAIMS ACT [Cal. Govt. Code §12650 <u>et</u>
NEW JERSEY, NEW MEXICO, NEW)	<u>seq.</u>]; DELAWARE FALSE CLAIMS AND
YORK, OKLAHOMA, RHODE ISLAND,)	FALSE REPORTING ACT [6 Del. C. §1201];
TENNESSEE, TEXAS, VIRGINIA,)	FLORIDA FALSE CLAIMS ACT [Fla. Stat.
WISCONSIN and the DISTRICT OF)	Ann. §68.081 <u>et seq.</u>]; GEORGIA FALSE
COLUMBIA, <u>ex rel.</u> JEROME PALMIERI,)	MEDICAID CLAIMS ACT [Ga. Code Ann.
)	§49-4-168 <u>et seq.</u>]; HAWAII FALSE CLAIMS
Plaintiffs,)	ACT [Haw. Rev. Stat. §661-21 <u>et seq.</u>];
)	ILLINOIS WHISTLEBLOWER REWARD
vs.)	AND PROTECTION ACT [740 Ill. Comp.
)	Stat. §175 <u>et seq.</u>]; INDIANA FALSE
ALPHARMA, INC.,)	CLAIMS AND WHISTLEBLOWER
)	PROTECTION ACT [Ind. Code Ann. §5-11-
and)	5.5-1 <u>et seq.</u>]; LOUISIANA MEDICAL
)	ASSISTANCE PROGRAMS INTEGRITY
ALPHARMA PHARMACEUTICALS, LLC,)	LAW [La. Rev. Stat. §437 <u>et seq.</u>];
)	MASSACHUSETTS FALSE CLAIMS LAW
And)	[Mass. Gen Laws ch. 12 §5 <u>et seq.</u>];
)	MICHIGAN MEDICAID FALSE CLAIMS
KING PHARMACEUTICALS, INC.)	ACT [Mich. Comp. Laws. §400.601 <u>et seq.</u>];
)	MONTANA FALSE CLAIMS ACT [Mont.
Defendants.)	Code Ann. §17-8-401 <u>et seq.</u>]; NEVADA
)	FALSE CLAIMS ACT [Nev. Rev. Stat. Ann.
)	§357.010 <u>et seq.</u>]; NEW HAMPSHIRE
)	FALSE CLAIMS ACT [N.H. Rev. Stat. Ann.

§167:61 et seq.]; NEW JERSEY FALSE CLAIMS ACT, N.J. Stat. § 2A:32C-1, et seq.; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat. Ann. §27-14-1 et seq.]; NEW YORK FALSE CLAIMS ACT [N.Y. State Fin. §187 et seq.]; OKLAHOMA MEDICAID FALSE CLAIMS ACT [Okla. Stat. tit. 63 §5053 et seq.]; RHODE ISLAND FALSE CLAIMS ACT [R.I. Gen. Laws §9-1.1-1 et seq.]; TENNESSEE FALSE CLAIMS ACT AND TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §4-18-101 et seq. and §71-5-181 et seq.]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. §36.001 et seq.]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann §8.01-216.1 et seq.]; WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT [Wis. Stat §20.931 et seq.]; and DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. § 1-1188.13 et seq.]

JURY TRIAL DEMANDED
(FILED IN CAMERA AND UNDER SEAL)

Jerome Palmieri (“Relator”), through his attorneys Morgan Carlo Downs & Everton, P.A., and Shelsby & Leoni, P.A., brings this qui tam action on behalf of the United States of America, the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and the District of Columbia (collectively “the States” or “Government Plaintiffs”), and in his own name against defendants Alharma, Inc., Alharma Pharmaceuticals LLC (herein called “Alharma”), a wholly-owned subsidiary of King Pharmaceuticals, Inc., and King Pharmaceuticals, Inc. (herein collectively “King” or “Defendants”) pursuant to the provisions of the False Claims Act.

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising out of defendants’ false and fraudulent billing, records and claims for payment to the Medicare, Medicaid, and related United States Government programs (herein, the “United States Government Health Programs”) providing for payment of pharmaceutical-related expenses, in connection with the prescription of a drug called “Flector Patch” that Alharma and King have distributed and marketed for the use by patients with acute pain due to minor strains, sprains, and contusions.

2. As set forth below, Alharma and King’s acts also constitute violations of the California False Claims Act, Cal. Gov’t Code §12650 et seq.; Delaware False Claims and Reporting Act, 6 Del C. §1201, et seq.; Florida False Claims Act, Fla. Stat. Ann. §68.081, et seq.; Georgia False Medicaid Claims Act, Ga. Code Ann. §49-4-168, et seq.; Hawaii False Claims Act, Haw. Rev. Stat. §661-21, et seq.; Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175, et seq.; Indiana False Claims and Whistleblower Protection Act, Ind.

Code Ann. §5-11-5.5-1, et seq.; Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §437, et seq.; Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5, et seq.; Michigan Medicaid False Claims Act, Mich. Comp. Laws. §400.601, et seq.; Montana False Claims Act, Mont. Code Ann. §17-8-401, et seq.; Nevada False Claims Act, Nev. Rev. Stat. Ann. §357.010, et seq.; New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61, et seq.; New Jersey False Claims Act, N.J. Stat. § 2A:32C-1, et seq.; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-14-1, et seq.; New York False Claims Act, N.Y. State Fin. §187, et seq.; Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053, et seq.; Rhode Island False Claims Act, R.I. Gen. Laws §9-1.1, et seq.; Tennessee Medicaid False Claims Act, Tenn Stat. 71-5-181, et seq.; Tennessee Health Care False Claims Act, Tenn Stat. 56-26-401, et seq.; Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §36.001, et seq.; Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1, et seq.; Wisconsin False Claims for Medical Assistance Act, Wis. Stat §20.931, et seq.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 1-1188.13 et seq.

3. As alleged herein, Alpharma and King caused thousands of false claims to be made on federal and state health care programs. Since at least late 2007, Alpharma and King systematically and improperly promoted a prescription drug, the Flector Patch, for unapproved, off-label uses. Alpharma and King gave substantial and illegal financial inducements to providers to encourage them to prescribe the Flector Patch and/or to switch from competitor products. Alpharma and King fraudulently conveyed to providers that the valid prescription for the Flector Patch was sixty (60) patches and that a patient could apply more than one patch to his body which resulted in the over-prescribing of the Flector Patch. These false claims cheated the federal and state governments out of funds that should not have been paid, unlawfully enriched

Alpharma and King and subjected patients to un-approved, non-effective, and unsafe uses and dosages of the Flector Patch.

4. Through their fraud, Alpharma and King:

- knowingly disregarded federal Food and Drug Administration (“FDA”) regulations concerning off-label promotion, and concealed such disregard from the regulatory authorities;
- knowingly misrepresented to physicians the evidence regarding the safety and efficacy of off-label usage of the Flector Patch;
- knowingly promoted off-label uses of the Flector Patch and dosages that were either not effective nor safe, and were not medically necessary; all for the purpose of significantly increasing the Flector Patch sales;
- illegally induced physicians to prescribe the Flector Patch for off-label uses in order to become part of the Flector Speakers Bureau, by which these physicians were then paid illegal financial inducements to continue to prescribe the Flector Patch;
- paid illegal financial inducements to prescribers to attend Speaker’s training which in fact exposed the physician to extensive Flector Patch promotion and induced the physician to write prescriptions for the Flector Patch to gain “clinical experience” which would enable the physician to be paid to conduct dinner programs.

I. JURISDICTION AND VENUE

5. The claims of this Complaint arise under the provisions of Title 31 U.S.C. § 3729, et seq., popularly known as the “False Claims Act.”

6. Based on the provisions of the False Claims Act, Relator seeks through this action to recover damages and civil penalties arising from false and fraudulent claims submitted by

Alpharma and King in violation of the False Claims Act and other laws and regulations governing the payment for and reimbursement by the United States Government Health Programs for prescription drugs.

7. This Court has jurisdiction over this action, pursuant to 31 U.S.C. §§3730, 3732(a), 28 U.S.C. § 1345, and 28 U.S.C. § 1331, because this action arises under the laws of the United States. This court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. As well, Defendants can be found in and transact business in this District. In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the State-law claims. Under 31 U.S.C. § 3730(e), and under the comparable provisions of the State statutes, there has been no statutorily relevant public disclosure of the “allegations or transactions” in the Complaint.

8. Venue is proper in the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because the acts proscribed by 31 U.S.C. §§ 3729, et seq., and complained of herein took place in the Eastern District of Pennsylvania. Venue is also proper pursuant to 28 U.S.C. § 1391 (b) and (c), because at all times material and relevant, defendants transact and transacted business in the Eastern District of Pennsylvania.

9. As required under the False Claims Act, Relator has provided to the Attorney General of the United States and the United States Attorney for the Eastern District of Pennsylvania simultaneously with the filing of this Complaint, a statement of all material evidence and information related to the Complaint. This disclosure statement supports the existence of false claims by Alpharma and King and possibly others in the Medicare, Medicaid and the United States Government Health Programs.

II. PARTIES

10. Relator Jerome Palmieri is a citizen of the United States and a resident of the State of Pennsylvania. He is the original source of the facts and information hereinafter set forth concerning the activities of King and its affiliated subsidiary, Alpharma. Relator brings this action based on his direct, independent, and personal knowledge and also on information and belief.

11. Relator has standing pursuant to 31 U.S.C. § 3730 to bring this Complaint for himself and on behalf of the United States Government.

12. Alpharma employed Relator Palmieri in February 2001 as a Sales Representative marketing Kadian, a sustained-release morphine prescription drug, in the Philadelphia area calling on physicians who treated chronic pain, specifically anesthesiologists, physiatrists, rheumatologists, and neurologists. Alpharma repeatedly recognized Relator as one of Alpharma's most successful sales representatives for Kadian.

13. In January 2009, King acquired Alpharma and employed Relator as a Senior Sales Representative for the Flector Patch and Avinza, calling on physicians who treated patients for chronic pain, recognized as pain which lasts more than three months in duration.

14. Alpharma, Inc., and Alpharma Pharmaceuticals, LLC are both headquartered in Bridgewater, New Jersey. Alpharma Pharmaceuticals, LLC is a wholly-owned subsidiary of King Pharmaceuticals, Inc, incorporated in the State of Tennessee in 1993 and whose headquarters is in Bristol, Tennessee. King Pharmaceuticals is principally engaged in the manufacture and sale of pharmaceuticals with total revenues in 2009 in excess of \$1.78 billion.

15. Alharma began selling Flector Patch in January 2008. Sales of Flector Patch grew 42.9% in 2009 compared to the launch year of 2008. Sales of Flector Patch were \$139 million in 2009 of which \$43 million was sold during the 4th quarter of 2009.

III. BACKGROUND

16. Alharma Pharmaceuticals, LLC, launched the sale of the Flector Patch in January 2008. After the acquisition of Alharma in December 2008, King Pharmaceuticals, Inc., marketed the Flector Patch. Alharma and King sell the Flector Patch throughout the United States, including Pennsylvania and the States, through a network of sales representatives who call on physicians, hospitals, and health care providers.

17. The Flector Patch is a topical patch containing 1.3% of diclofenac epolamine, a nonsteroidal anti-inflammatory drug (NSAID), the same class of drugs that includes ibuprofen and naproxen.

18. The Flector Patch is the only prescription NSAID patch and is applied directly on the area of the injury. Unlike an oral medication, the active ingredient in the Flector Patch is absorbed through the skin and goes directly to the site of pain rather than traveling through the stomach and digestive tract.

19. The dosing for Flector Patch is one patch to the most painful area, twice a day.

20. Specifically, the Flector Patch is only approved by the FDA for use as a “topical treatment of acute pain due to minor strains, sprains, and contusions [bruises].” However, the Flector Patch is substantially more expensive than other existing, generic treatments for these types of conditions and injuries. Thus, the Flector Patch was not and is not competitive in the market for its FDA-approved indications.

21. Significantly, in Europe, Flector Patch is approved for the treatment of conditions such as osteoarthritis, rheumatoid arthritis, menstrual pain, bursitis, ankylosing spondylitis, tendonitis and other inflammatory conditions but Alpharma chose not to seek approval by the FDA for these indications. Instead, Alpharma and King chose to fraudulently convey to providers the fact that Flector Patch was used successfully in Europe to treat this wide variety of ailments as a means to illegally induce these providers to prescribe Flector Patch off-label for these conditions, despite the fact that Flector Patch's only FDA approved indication is for the topical treatment of acute pain due to minor strains, sprains, and contusions.

22. Since Flector Patch's approval nearly 3 years ago, King has not sought to expand its approved indication.

23. Flector Patch's narrow FDA-approved indication limits the potential sales growth of the drug, particularly in view of the fact that the numerous other approved pain medications are also available to the public. Specifically, other non-steroidal anti-inflammatory (NSAID) drugs, the class of medication for Flector Patch, includes a wide variety of generic and Over-the-Counter (OTC) drugs such as naproxen (Aleve, Anaprox), aspirin (Anacin, Ascriptin, **Bayer**, Bufferin, Ecotrin, **Excedrin**), ibuprofen (Motrin, Advil, Nuprin), and Magnesium salicylate (Arthritab, Bayer Select, Doan's Pills, Magan, Mobidin, Mobogesic). To expand the market for the Flector Patch, Alpharma and King resorted to illegally marketing the drug as a suitable treatment for chronic pain conditions—even though the Flector Patch has not been approved by the FDA for the indication of chronic pain. The Flector Patch's very specific approved indications are for acute – not chronic – pain, and only for the specifically defined conditions of “strains, sprains, and contusions.”

24. Federal and state laws prohibit Alpharma and King from engaging in such off-label marketing.

IV. THE PROHIBITION AGAINST MARKETING DRUGS FOR OFF-LABEL USES

25. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

26. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

27. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which must also be reviewed and approved by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

28. Under section 401 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA") – which expired on September 30, 2006 – if a manufacturer wished to market or promote an approved drug for alternative uses (*i.e.*, uses not listed on the approved label) the manufacturer was required to resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until subsequent approval of the new

use was granted, the unapproved use was considered to be “off-label.” “Off-label” refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug’s labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

29. The FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication. However, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

30. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws: (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose; and (2) a manufacturer illegally “misbrands” a drug if the drug’s labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

31. An off-label use of a drug can cease to be off label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b) & (c).

32. In addition to prohibiting manufacturers from directly marketing and promoting a product’s off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1)

manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products; and (2) manufacturer support for Continuing Medical Education (“CME”) programs that focus on off-label uses.

33. With regard to the first practice, disseminating written information, the FDAMA only permitted a manufacturer to disseminate information regarding off-label usage in response to an “unsolicited request from a health care practitioner.” 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer was permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer submitted an application to the FDA seeking approval of the drug for the off-label use; provided the materials to the FDA prior to dissemination; and the materials themselves were in an unabridged form and were not false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1. Even these limited exceptions allowing the distribution of off-label information were closed when section 401 of the FDAMA expired on September 30, 2006. Although the FDA is currently considering adopting new rules to replace the expired ones, no such new rules are yet effective.

34. With regard to manufacturer involvement in CME programs, the FDA’s examination of these practices led to publication of an agency enforcement policy in 1997 entitled, “Guidance for Industry: Industry-Supported Scientific and Educational Activities,” 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is “free from the supporting company’s influence and bias.” *Id.* These factors include, among others, an examination of the relationship between the program provider and supporting company, the company’s control of content and selection of presenters, whether there is a meaningful disclosure of the company’s

funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. *Id.* The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

35. In sum, the FDCA prohibits drug companies from promoting approved drugs for unapproved uses or from making misleading claims as to the drug's safety or effectiveness. *See* 21 U.S.C. §§ 331, 352, 355(d). This off-label regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body: the FDA.

V. WRONGFUL ACTS OF ALPHARMA AND KING

36. To increase sales of the Flector Patch, a drug with a limited market for its approved uses, Alpharma and King have engaged in an extensive, widespread and systemic fraudulent marketing scheme. As described below, the scheme has five integral components: (1) aggressive and improper off-label promotion of unapproved uses of the Flector Patch; (2) payment of illegal kickbacks to providers to induce them to prescribe the Flector Patch, both on-label and off-label; (3) a scheme designed to fraudulently increase Flector Patch sales significantly by telling physicians that the proper prescription for Flector Patch is sixty (60) patches, or two (2) Flector Patches a day for thirty (30) days when, in fact, that is patently false; and telling providers that a patient can apply Flector Patches to more than one injured area; (4) misleading and false comparative selling against other drugs claiming unsubstantiated efficacy

and superiority; and (5) overstating the safety and efficacy of the Flector Patch by omitting and minimizing the risks associated with the Flector Patch.

37. Alpharma and King participated in the following practices, which defrauded the United States through the United States Government Health Programs. These practices included submitting false claims to the United States for payments, resulting in payments to Alpharma and King in violation of the False Claims Act.

A. Illegal Physician Inducements

38. Alpharma and King have violated federal anti-kickback laws by paying and offering to pay financial and other inducements to physicians and other providers to influence their Flector Patch prescribing practices.

39. Alpharma and King concocted this scheme because the legal market for the Flector Patch was limited, due to both its price and its limited approved indications. Flector Patch is only approved by the FDA for the treatment of “acute pain due to minor strains, sprains, and contusions.” Other drugs commonly used to treat such injuries, generic and OTC drugs such as aspirin, naproxen, and ibuprofen, are substantially cheaper—sometimes 30 times cheaper—than the Flector Patch.

40. Alpharma and King recruited physicians to be on their “Speakers Bureau” and gave these physicians excessive payments (including lavish accommodations, meals, travel, and other benefits) to attend speaker training.

41. Physicians who were chosen to be on the Speakers Bureau were promised the opportunity to conduct many speaking engagements at excessive rates, e.g. \$2700.00 per talk, once they had gained “clinical experience with the Flector Patch” which created an illegal inducement for the physician to prescribe Flector Patch or to otherwise cause its prescription.

42. Contrary to federal rules and the PhRMA code, physicians were chosen by the individual Alpharma and King sales representative who, in most instances, selected a doctor who treats chronic pain conditions and one who was a high prescriber of Kadian, a long-acting sustained release morphine sulphate drug that is prescribed for chronic pain. The majority of these physicians chosen to be a speaker for the Flector Patch were physicians who do not primarily treat acute pain, the types of conditions that the Flector Patch is approved by the FDA to treat, i.e., "acute pain due to minor strains, sprains, and contusions [bruises]."

43. Sales representatives selected a physician with whom they had a personal relationship and one whom they believed would prescribe Flector Patch for the sales representative based on that relationship. By so selecting a physician to attend speaker training, the sales representative gave the physician the opportunity to receive a generous honorarium, travel to a resort free of charge, develop a referral network, and be eligible for future speaking honorariums.

44. These inducements were provided to win access to these high prescribing physicians for marketing activities and to induce them to prescribe more Flector Patches.

45. The majority of physicians recruited for the Speaker's Bureau were specialists in the fields of chronic pain management, rheumatology, neurology, and anesthesia. The inducement of these physicians to prescribe the Flector Patch in itself is off-label promotion of the drug as these physicians do not customarily and routinely treat acute minor conditions of strains, sprains, and contusions.

46. Additionally, these Speaker Boards offered the physician the opportunity to speak to primary care physicians from whom they would like to receive referrals, thereby offering the

speaker the opportunity to create a “referral network” with these primary care physicians which in itself is an illegal inducement.

47. Alpharma and King recruited an excessive number of physicians to the Speaker’s Bureau, allowing each representative to select a physician to be a speaker. This was purely a scheme to remunerate physicians to prescribe the Flector Patch as the majority of these physicians trained to be speakers were not, in fact, utilized as speakers.

48. Alpharma and King chose doctors to be speakers based on the strength and history of their Kadian and Flector Patch prescriptions and the potential to grow their market, rather than on their leadership, speaking skills, or distinction in professional practice.

49. For example, Alpharma and King have promoted off-label uses of Flector Patch to Dr. Theresa Lawrence-Ford, a rheumatologist in Atlanta. Dr. Lawrence-Ford regularly treats patients with rheumatoid arthritis, osteoarthritis, lupus, and fibromyalgia. She generally prescribes opioids to treat the chronic pain that is inherent in some patients with these diseases. These diseases are chronic, not acute, in nature, and are not within the approved prescribing label for the Flector Patch.

50. Another physician asked to be a Flector Patch speaker and to attend the Speaker’s Training, and receive a \$1500 payment to attend the training, is Dr. Amer Kazi, a neurologist, pain management specialist, and expert in the management of migraines from South Bend, Indiana.

51. Many anesthesiologists were invited to the Flector Patch Speaker’s training: Andy Kaufman, from Hillsdale, N.J., Michael McCauley, from Tempe, AZ, Krishna Nadar, from Louisville, KY, and Raphael Miguel of Tampa, FL. These specialists in pain management do not treat acute conditions and practice in settings in which a patient with an acute injury could not be

seen within a timely fashion. These physicians are interventional pain specialists whose practices generally encompass diagnoses that are chronic in nature and whose therapies are invasive and include facet blocks, laminectomies, electrical stimulation, intrathecal pumps, TENS units, and procedures.

52. Of the 200 physicians currently trained as Flector Patch speakers, over 60% of these physicians are specialists in the fields of anesthesia, pain management, neurology, or rheumatology. These medical specialties are not ones that would be typically treating “minor strains, sprains, or contusions,” yet Alpharma and King induced these physicians to prescribe Flector Patch.

53. It is inappropriate to hire physicians who specialize in the treatment of chronic pain to become “experts” on a drug whose only on-label indication is for conditions—sprains, strains, and contusions—that such chronic pain doctors rarely treat. The fact that chronic pain physicians are targeted by Alpharma and King demonstrates that Alpharma and King are promoting Flector Patch for off-label uses.

54. Alpharma and King select physicians to attend speaker training, to serve as a “consultant,” and/or to give speeches promoting Flector Patch based on how much Flector Patch the physician prescribes, has the potential to prescribe, or as an inducement for prescribing other Alpharma or King drugs such as Kadian or Embedda.

55. In the case of Flector Patch, Alpharma and King maximized profits by undertaking a fraudulent scheme by which Alpharma and King paid substantial and illegal financial inducements to promote both on-label and off-label prescriptions of Flector Patch.

B. Illegal Off-Label Marketing

56. To grow sales of Flector Patch, a drug with limited approval and strong market competition, Alpharma and King have engaged in an extensive fraudulent marketing scheme by promoting Flector Patch for uses and dosages that were not approved by the FDA or for reimbursement by the United States Government Health Programs.

57. As part of this campaign, Alpharma and King have targeted doctors who specialize in the treatment of chronic pain, neurological conditions, and rheumatological conditions. That Alpharma and King are targeting these physicians is, itself, evidence of off-label promotion because these doctor specialties rarely if ever treat the types of injuries for which Flector Patch is legally indicated—namely, sprains, strains, and contusions.

58. Alpharma and King target physicians who prescribe a high amount of Lidoderm, a drug that is indicated for the treatment of post-herpetic neuralgia and a drug that many chronic pain physicians use (off-label) for the treatment of chronic pain conditions. Targeting Lidoderm prescriptions for switching to Flector Patch would result in off-label use of Flector Patch.

59. Alpharma and King target physicians who are high prescribers of Celebrex, an NSAID that is indicated for osteoarthritis, rheumatoid arthritis, ankylosing spondylitis (degenerative joint diseases), primary dysmenorrhea (painful menstruation), acute pain of all types, and the reduction in adenomatous colorectal polyps. Targeting Celebrex prescribers would most likely result in a high degree of off-label use of Flector Patch.

60. Alpharma and King target physicians who are high prescribers for Voltaren Gel, an NSAID indicated for the relief of the pain of osteoarthritis of joints such as knees and hands. By asking and encouraging physicians to switch Voltaren Gel prescriptions to Flector Patch is an illegal marketing ploy that results in off-label use of Flector Patch.

61. The highly aggressive marketing strategy for Flector Patch was driven by Lucrative off-label markets. On August 21, 2007, Alpharma announced that it “had entered into a licensing agreement to market the Flector Patch, the first topical NSAID for pain to be marketed in the US.” In its press announcement, Alpharma remarked that it was “excited about the potential of Flector Patch, particularly when combined with the current Kadian product, which will allow the company to leverage Alpharma's pain expertise and existing sales force.” In this press release and announcement, Alpharma was revealing its plan to fraudulently and illegally market Flector Patch as a “pain drug” to its existing Kadian customers, all providers treating chronic pain conditions and prescribing chronic pain medications.

62. During Alpharma's press announcement, Alpharma revealed its strategy for the Flector Patch acquisition which included the recent market trends for the NSAID market: (1) a decline in COX-2 usage resulting from well-publicized safety concerns and (2) corresponding growth in NSAID usage. This announcement clearly demonstrates Alpharma's plan to aggressively fraudulently market Flector Patch for indications far beyond its approved indications.

63. The press announcement further explained that Alpharma had done considerable market research with high prescribers of NSAIDs, which showed that “the market continues to have significant unmet medical needs.” This market includes many indications and uses which are off-label for Flector Patch as its approved FDA indications are very narrow, being only for “minor sprains, strains, and contusions.”

64. Alpharma's aggressive off-label marketing scheme was further revealed by Alpharma's disclosure that “Flector Patch delivers the anti-inflammatory and analgesic properties of the proven NSAID, diclofenac, a drug that doctors are comfortable with in terms of

its ability to treat pain.” Diclofenac is the active ingredient in many medications which are approved for many indications that are off-label for Flector Patch.

65. Alparma further disclosed that Flector Patch’s “innovative NSAID delivery system...[is one in] which physicians view as a strong advantage over current oral NSAIDs.” Alparma positioned Flector Patch from the beginning as a drug equal to oral NSAIDs in terms of efficacy in all indications despite the fact that Flector Patch cannot legally be prescribed for all the same indications of oral NSAIDs.

66. Alparma announced a “Physicians Survey in which physicians indicated that they anticipated broad use [of the] Flector Patch in variety of acute pain situations, particularly for patients who have had specific concerns regarding oral NSAIDs.” This scheme to market Flector Patch for a “variety of acute pain situations” was at the core of Alparma’s illegal and fraudulent scheme to sell Flector Patch for off-label use.

67. Alparma announced that “Doctors would substitute Flector Patch for oral NSAIDs and COX-2s, indicating significant market potential.” Alparma planned and schemed to illegally and fraudulently market Flector Patch for off-label uses from the moment it bought the Flector Patch.

68. Alparma and King planned to illegally market Flector Patch for all types of pain relief, both acute and chronic, including the lucrative indication of osteoarthritis.

69. Alparma and King drove profits of Flector Patch by extensively marketing Flector Patch for non-approved usages. This scheme violated the FDA laws and regulations concerning marketing of drugs; violated federal and state health insurance drug reimbursement statutes and regulations; and violated federal Anti-Kickback laws. It is estimated to have already resulted in the submission of hundreds of thousands of false claims for federal and state health

care program reimbursement, pursuant to Federal False Claims Act and the States False Claims Act statutes.

70. Despite the lack of FDA approval for indications such as osteoarthritis, rheumatoid arthritis, and other acute and chronic pain indications, Alpharma and King developed and employed a marketing strategy that promoted Flector Patch for unapproved and off-label use and dosages.

71. Alpharma and King used a variety of methods including direct detailing using information provided to field sales representatives, providing free samples of Flector Patches to physician specialties that did not treat acute sprains, strains, and contusions (the only approved indication for Flector Patch), and allowing speakers to talk about the uses of Flector in Europe, most of which are off-label and unapproved in the United States.

72. Although federal regulations prohibit Alpharma and King from promoting Flector Patch for non-FDA approved uses, it is permitted to distribute information created by third parties that describe off-label uses of Flector Patch provided such material was only distributed in response to non-solicited requests from physicians. Alpharma and King circumvented this narrow exception by encouraging sales representative to solicit physicians to “request” medical information regarding Flector Patch. Business Reply Cards were supplied to sales representative in the amount of fifty (50) per month for use in this type of off-label and unapproved information.

73. Alpharma and King provided generous free samples of Flector Patches to specialists who did not treat the FDA-approved indications of “acute sprains, strains, and contusions.” Alpharma and King sales representatives were provided with cases and cases of free samples of Flector Patches and were told to liberally distribute these free samples to chronic

pain physicians, rheumatologists, oncologists, and neurologists. The purpose and policy of this practice was/is to promote Flector Patch for non-FDA approved uses. This policy and practice is also an inducement to physicians to “support” the sales representative who is providing these generous free samples by writing prescriptions of Flector Patch.

74. Alpharma and King promoted the proactive dissemination of medical letters when unsolicited by the healthcare provider which enabled them to promote off-label and unapproved uses of Flector Patch.

C. Fraudulently Promoting Flector Patch for Doses Higher than Approved

75. The FDA has approved the dosage for the Flector Patch as “one (1) patch to the most painful area twice a day.” Alpharma and King directed sales representatives to illegally and fraudulently promote Flector Patch to be applied to more than one area of a patient, directly contradicting the FDA-approved safe dosage and directly increasing the sales of Flector Patch.

76. The FDA-approved dosage and administration for the Flector Patch is to “Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals.” Alpharma and King’s marketing scheme to promote the use of more than one patch at a time is contrary to the FDA-approved dosage and the dosage approved for the safety of Flector Patch.

77. Alpharma and King utilized their substantial sales force to improperly promote excessive dosages of Flector Patch. In particular, Alpharma and King developed marketing and promotional materials that direct a physician to write a Flector Patch prescription as “Flector Patch, 1 patch BID, # 60,” which would result in sixty (60) Flector Patches being dispensed.

78. Alpharma and King, by contending that a valid Flector Patch is written as “#60” or sixty patches, fraudulently conveyed that the proper dosage for Flector Patch is for thirty days

and/or that the Flector Patch can only be dispensed for sixty (60) patches when, in fact, the health care provider may prescribe the Flector Patch in any quantity or number.

79. Each and every marketing piece contains a picture of a sample prescription that says "Flector Patch - 1 patch BID - #60." Sales representatives were instructed to place these marketing pieces in the physician's sample closets directly on the shelf which held the Flector Patch samples.

80. In addition, Alpharma and King sales representatives distributed "prescription stampers" for Flector Patch that contained this exact verbiage that was to be stamped onto the physician's prescription, circumventing the possibility that the physician would write a prescription for an amount less than 60 patches. It also falsely promoted the view that a valid Flector Patch script was 60 patches. A legal and compliant stamp would have a space for the physician to write the number of patches he was prescribing.

81. Strains, sprains, and contusions are injuries that may cause acute pain from 48 hours to 4 weeks, depending on each individual injury. By promoting the sale of *each* Flector Patch prescription to be dispensed for sixty patches, Alpharma and King fraudulently induced the physician and the pharmacies to sell more Flector Patches than necessary for a large majority of patients.

82. Each patient should be treated individually and each acute sprain, strain, and contusion is unique and individual. By promoting and fraudulently conveying to physicians and pharmacies that a valid Flector Patch prescription is for sixty (60) patches, Alpharma and King induced the fraudulent payment of hundreds of thousands of claims. The average sale for sixty Flector Patches is \$381.00. A patient with a contusion that causes acute pain for three days that is prescribed Flector Patch in this fraudulent manner of sixty patches would result in an

overpayment of \$324.00 or ten times the amount of Flector Patches that are required for a true on-label dosage.

83. The safety of the Flector Patch is overstated as well as the clinical trials for Flector Patch were conducted at levels and dosages consistent with the injuries. In fact, a key clinical trial for Flector Patch, the Jousselein study, studied the efficacy and safety of the Flector Patch for patients with minor ankle sprains for three days. The Carr clinical trial studied the safety and efficacy of Flector Patch for patients using the drug for 14 days.

84. This marketing scheme promotes the use of the Flector Patch in direct contradiction to the approved dosage for Flector Patch: “the lowest effective dose for the shortest duration consistent with individual patient treatment goals.” Thus, this marketing scheme is illegal, fraudulent, and off-label. Not only does this illegal and fraudulent marketing scheme cause the payment of false prescription claims, it endangers the health and safety of the public.

D. False Representation About the Safety and Efficacy of the Flector Patch

85. Alpharma and King’s marketing strategy to promote the usage of multiple Flector Patches for dosages higher than recommended or needed, and for a duration of thirty days despite the need, demonstrate a disregard for the safety of the patients using the Flector Patch. At no time did Alpharma and King instruct their sales representatives or physician-speakers that the safety information for which the Flector Patch was approved is for dosages far below what is being marketed.

86. Alpharma And King marketed the Flector Patch as a “safe alternative for oral NSAIDs” and widely promoted the drug as being “safer than other NSAIDs.” Sales Representatives told providers that the “Important Safety Information and Warnings” for Flector Patch were “class labels” and were required by the FDA because the active ingredient in Flector

Patch was diclofenac, an NSAID and falsely gave providers the impression that Flector Patch was, in fact, safer than oral NSAIDs and other forms of diclofenac.

87. This false and fraudulent marketing practice affirmatively misrepresented Flector Patch's side effects to prescribers. In fact, Flector Patch, as all NSAIDs, "may cause an increased risk of serious CV thrombotic events, myocardial infarction, and stroke, and can be fatal." Sales representatives did not include this warning in their details to physicians and, in fact, misrepresented the warning as a "class warning" only.

88. The FDA-approved safety information says that "Flector Patch should not be given to patients who have experienced allergic-type reactions after taking aspirin or other NSAIDs" yet sales representatives routinely touted the Flector Patch as safe for patients that "cannot tolerate oral NSAIDs."

89. Alpharma and King's marketing strategy stresses that Flector Patch is safer than oral NSAIDs and COX-2 inhibitors (Celebrex, Vioxx and Bextra) which have been widely criticized for their adverse effect of "new onset or worsening of hypertension, contributing to increased incidence of CV events." Alpharma and King sales representatives and their physician speaker advocates promote that Flector Patch does not have this same adverse side effect when, in fact, it most certainly contains the exact same warning as the COX-2 inhibitors.

90. Alpharma and King falsely promote the Flector Patch as a safe alternative for patients who cannot tolerate NSAIDs and convey to the providers that Flector Patch has no adverse side effects and is a very safe drug, when in effect, the FDA has listed lengthy warnings, contraindications, precautions, and adverse events. The omission of these safety warnings is fraudulent and misleading.

91. This improper and fraudulent minimization of health risks when dosed with the Flector Patch disregarded patient safety, resulted in unapproved, off-label uses of Flector Patch, and exposed patients to unnecessary safety risks in an effort to maximize sales of Flector Patch.

92. The marketing and sales practices of Alpharma and King did not present the Flector Patch in a fair and balanced manner as the risks and safety concerns associated with Flector Patch and the narrow FDA-approved indications of the Flector Patch were not communicated to physicians; rather, Alpharma and King chose to misrepresent the approved prescribing information as well as to broaden the indications for Flector Patch.

VI. ALPHARMA AND KING ILLEGALLY ASSERTED SUPERIORITY CLAIMS TO COMPETITOR DRUGS

93. Alpharma and King engaged in a fraudulent and illegal marketing campaign in which they asserted claims and superiority to competitor drugs without substantial evidence. Flector Patch sales representatives were instructed to competitively sell against Celebrex, Lidoderm, and Voltaren Gel even though these drugs had different indications than Flector Patch.

94. Despite the lack of any clinical trials yielding clinical evidence to support claims of superiority and the absence of head-to-head comparative trials in which Alpharma and King could assert equal efficacy and safety, Alpharma and King promoted Flector Patch with unsubstantiated comparative claims with other drugs such as NSAIDs, Celebrex, Voltaren Gel, and Lidoderm.

95. Alpharma developed a 20-page "Flector Patch Competitive Backgrounder" that was used to train their sales representatives. This training booklet outlined information such as dosing, method of action, clinical trials, key messages, and approved indications for drugs that

Alpharma considered to be their competitors: Lidoderm, Celebrex, and Voltaren Gel. This sales training booklet provided the sales representatives with a “potential positioning” for each competitor and trained the sales representatives to sell against these drugs.

96. Alpharma and King have no clinical trials comparing Flector Patch to Celebrex, Voltaren Gel, Lidoderm, any NSAID, or, in fact, against any other drug. All three of the clinical trials submitted to the FDA compared Flector Patch to placebo, or no drug. Thus, Alpharma and King cannot make any comparative statements.

97. The FDA’s policies proscribe comparative selling in the absence of “substantial evidence” of two clinical trials with the primary endpoint of a head-to-head comparison. Alpharma and King directed their sales representatives to compare the package inserts of Celebrex, Lidoderm, and Voltaren Gel with Flector Patch which improperly drew the inference that a comparison could be made. This was patently false.

98. Alpharma and King directed their sales force to make false and misleading promotions in the form of comparative sales statements in an effort to switch prescriptions from Celebrex, Lidoderm, NSAIDs and Voltaren Gel to Flector Patch.

VII. PRESCRIPTION DRUG PURCHASES UNDER FEDERAL AND STATE HEALTHCARE PROGRAMS

A. Medicare

99. Medicare is a federally-funded health insurance program primarily benefiting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. The Medicare program is administered through the Department of Health and Human Services’ Centers for Medicare and Medicaid Services.

100. The Medicare program has four parts: Part A, Part B, Part C and Part D. Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

101. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program under Part D. The first stage of the Part D program, in effect from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program. Starting in 2006, the Medicare Program began providing subsidized drug coverage for all beneficiaries.

B. Medicaid

102. Medicaid was also created in 1965 under Title XIX of the Social Security Act. Funding for Medicaid is shared between the Federal Government and those states participating in the program. Thus, under Title XIX of the Social Security Act, 42 U.S.C. § 1396, *et seq.*, federal money is distributed to the states, which in turn provide certain medical services to the poor.

103. Historically, the Medicaid program has subsidized the purchase of more prescription drugs than any other program in the United States.

104. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs.

105. Federal Medicaid regulations require each state to designate a single state agency responsible for the Medicaid program. The agency must create and implement a “plan for medical assistance” that is consistent with Title XIX and with the regulations of the Secretary of HHS (“the Secretary”). After the Secretary approves the plan submitted by the state, the state is entitled each quarter to be reimbursed for a percentage of its expenditures made in providing certain types of “medical assistance” under the plan. 42 U.S.C. § 1396b(a)(1).

106. Individuals may be “dual eligible” for both the Medicare program (as the primary insurer) and the Medicaid program (as the secondary insurer).

C. Other Federal and State-Funded Health Care Programs

107. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and federal workers' compensation programs.

108. TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependants affiliated with the armed forces.

109. CHAMPVA, administered by the United States Department of Defense, is a health care program for families of veterans with 100 percent service-connected disability.

110. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

111. States provide health care benefits to certain individuals, based either on the person's financial need, employment status, or other factors. To the extent those programs are covered by that State's False Claims Act, those programs are referred to in this Complaint as "State-funded health care programs."

D. Direct Purchases By Federal Agencies

112. In addition to reimbursing drug purchases through Medicare, Medicaid, and other federal and state health care programs, the United States is a significant direct purchaser of prescription drugs through various federal programs, including but not limited to the following:

113. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug

benefit. The system serves approximately four million veterans. The VA directly purchases prescription drugs that are dispensed through these facilities and programs.

114. The Department of Defense (“DOD”) provides prescription drug coverage to approximately eight million active duty personnel, retirees, and their families through three points of service: military treatment facility outpatient pharmacies, TRICARE managed care contractor retail pharmacies, and the National Mail Order Pharmacy Program. DOD negotiates independent contracts to purchase the majority of the prescription drugs provided through these programs.

E. Providers Must Submit True Claims, and Correct Any Known Prior False Statements

115. Federal law specifically prohibits providers from making “any false statement or representation of a material fact in any application for any . . . payment under a Federal health care program.” See 42 U.S.C. §1320-a-7b(a)(1).

116. Similarly, Federal law requires providers who discover material omissions or errors in claims submitted to Medicare, Medicaid, or other Federal health care programs to disclose those omissions or errors to the Government. See 42 U.S.C. §1320-a-7b(a)(3).

117. The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program, the Medicaid program, and other Federal and State-funded health care programs. See, e.g., 42 CFR §§1003.105, 1003.102(a)(1)-(2).

VIII. DEFENDANTS ALPHARMA AND KING’S ANTI-KICKBACK STATUTE VIOLATIONS CAUSED FALSE CLAIMS TO BE SUBMITTED TO THE GOVERNMENT

A. The Federal Anti-Kickback Statute Prohibits Offering Financial Incentives To Induce Physicians To Prescribe Drugs That Will Be Paid For With Federal Funds.

118. The federal Anti-Kickback Act, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the offer or payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to over-utilization or poor quality of care.

119. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by a federal health care program. *Id.* The law not only prohibits outright bribes, but also prohibits any payment by a drug company that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

120. Such illegal inducement relationships between drug companies and physicians endanger patients and harm the Government Plaintiffs because, as here, they encourage unnecessary treatments, contaminate the free exercise of medical judgment by providers, limit patient options and lead to higher federal and state payments for prescription drug benefits. The Anti-Kickback Statute was promulgated to thwart such dangerous practice of medicine.

121. The remuneration paid by Defendants Alpharma and King and accepted by physicians all across the country, as alleged in detail herein, fit squarely within the Anti-Kickback Statute's definition of illegal remuneration.

122. As alleged herein, in violation of the Anti-Kickback Statute, Defendants Alpharma and King paid, and physicians accepted unlawful remuneration, including cash payments thinly-veiled as speaker fees and/or speaker's training, and other gratuities as *quid pro quo* for volume prescription writing of the Flector Patch to chronic pain patients, notwithstanding Alpharma and King's knowledge of the prohibition of offering, paying or receiving items of value in exchange for arranging the purchase of any good paid for in whole or in part by the federal government.

123. Defendants Alpharma and King entered into unlawful inducement relationships in violation of the Anti-Kickback Statute with physicians who do not routinely treat acute pain conditions and other medical professionals nationwide.

124. Although "safe harbor" regulations exist to protect certain relatively innocuous and even beneficial commercial arrangements, no such provision protects the kickbacks paid by Alpharma and King.

125. Alpharma and King prevented the Government Plaintiffs from knowing of Anti-Kickback Statute violations by concealing such agreements.

B. Defendants Alpharma and King's Anti-Kickback Statute Violations Are Predicate Acts Giving Rise to Liability Under the Government Plaintiffs' False Claim Acts.

126. The Anti-Kickback Statute works hand in glove with the False Claims Act. As a matter of law, violations of the Anti-Kickback Statute state a cause of action under the False Claims Act. Indeed, compliance with the Anti-Kickback Statute, as well as all other relevant

laws and regulations, is a condition of payment by Medicaid for prescription drug claims. 42 U.S.C. § 1320a-7b(b).

127. Thus, where conduct that violates the Anti-Kickback Act results in goods and services (here, the Flector Patch) provided to Medicare and Medicaid beneficiaries, that good or service is *ineligible* for reimbursement under Medicare, Medicaid, the VA and CHAMPUS/Tricare payments rules and federal law.

128. Thus, as a matter of law, prescription drugs and other products purchased in violation of the Anti-Kickback Statute are ineligible for Government reimbursement. By and through the covert payment of illegal kickbacks, Alpharma and King defrauded, among other things, Medicaid-participating pharmacies into presenting reimbursement claims for the Flector Patch to the Government Plaintiffs containing the false certification that the claim was submitted in compliance with the Anti-Kickback Statute and other applicable regulations.

129. The Government Plaintiffs would appropriately have denied the Flector Patch reimbursement claims if they had knowledge that the Flector Patch prescription giving rise to the claim was the product of an illegal kickback arrangement.

130. Defendants Alpharma and King, acting in concert with physicians, caused, among other things, Medicaid-participating pharmacies all across the country to submit claims that were rendered ineligible for reimbursement by Alpharma and King's violations of the Anti-Kickback Statute as well as caused such pharmacies to explicitly falsely certify that they were acting in compliance with all applicable laws and regulations, including the Anti-Kickback Statute, for each and every claim the pharmacies submitted. The pharmacies' certifications Alpharma and King caused to be submitted to the Government, however, were false when made.

131. Such pharmacies reasonably and justifiably relied upon the validity and medical appropriateness of the Flector Patch prescriptions.

132. Alpharma and King's illegal scheme had one intended purpose and result – increasing Flector Patch profits – and therefore certified claims for the Flector Patch prescriptions instead of cheaper alternatives were submitted to the Government Plaintiffs for payment by pharmacies throughout the nation. Accordingly, at all times relevant to the Complaint, Alpharma and King acted with the requisite intent.

133. The result of Alpharma and King's scheme was a dramatic increase in the number of claims submitted to the Government Plaintiffs for the higher priced Flector Patch, which led to higher revenue for Alpharma and King. Alpharma and King's increased revenues, and the correspondingly-increased cost to the Government healthcare programs, were the direct, intended, and foreseeable result of the unlawful kickback payments made by Alpharma and King to physicians who do not routinely treat acute pain conditions.

134. Alpharma and King's liability under §§ 3729(a)(1)(A) and (B) of the Federal False Claims Act, §§ 68.082(a) and the analogous laws of the Plaintiff States arises from Alpharma and King's overt and willful participation in causing the basis for false claims to be made through the establishment of illegal and corrupt financial relationships.

135. Alpharma and King's conduct is also punishable under § 3729(a)(1)(C) of the Federal False Claims Act, and the analogous provisions of the remaining Plaintiff States' laws, for entering into unlawful conspiracies with the intent to defraud the Government.

COUNT I
FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(A)

136. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

137. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

138. A significant percentage of patients who use or have been prescribed the Flector Patch off-label for non-medical necessary uses as a result of Defendants' unlawful off-label marketing campaign are persons whose prescriptions are paid for in whole or in part by Medicare, Medicaid, TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and federal workers' compensation programs.

139. At all times relevant and material to this Complaint, Defendants have induced a misallocation of Government-Plaintiffs' funds on a nationwide basis through a pattern of fraudulent conduct, as alleged herein. Defendants intentionally concealed its national campaign to market the Flector Patch for un-approved indications and medically unnecessary uses for the purpose of, and with the effect of, unlawfully increasing purchases of the Flector Patch prescriptions by the Government Plaintiffs that would not have purchased them but for Defendants' active concealment of its unlawful Flector Patch marketing campaign.

140. By the conduct alleged in this Complaint, Defendants have knowingly and foreseeably caused the submission of false claims for payment or approval that Defendants knew to be ineligible for reimbursement and the cost of which would be borne by federal and state governments by and through government-funded health plans, to be presented to officers and employees of the federal and state governments. Defendants' conduct includes its deceptive and

illegal scheme to expand off-label use of the Flector Patch by, among other things, 1) marketing the Flector Patch in a misleading and/or disingenuous way for off-label uses and 2) orchestrating a kickback scheme pursuant to which, in sum, it paid physicians in cash and in kind in exchange for writing off-label prescriptions of the Flector Patch. As a result, the United States government paid the false claims submitted for the Flector Patch drugs by pharmacies, resulting in great financial loss to the Government Plaintiffs.

141. Defendants' conduct constitutes the intentional violation of the Federal False Claims Act.

142. By virtue of the above-described acts, among other things, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval, and continues knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees, or agents of the United States, for the Flector Patch.

143. The claims for the Flector Patch caused to be presented by Defendants constitute false claims, because, among other things, Medicare/Medicaid reimbursement is not available for non-medically accepted indications or non-medically necessary uses of prescription drugs as alleged herein.

144. By virtue of the above-described acts, Defendants knowingly and intentionally conspired to, and caused false claims for payment to be presented for the Flector Patch from the implementation of its kickback scheme. Defendants' kickback scheme violated the Anti-Kickback Statute and caused the submission of false claims to the Government.

145. It was the intended and foreseeable effect of Defendants' kickback scheme to cause pharmacies to routinely present thousands of false claims requesting reimbursement for expensive Flector Patch prescriptions.

146. The amounts of the false or fraudulent claims to the United States were material.

147. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities, across the United States. Relator has no control over or dealings with such entities and has no access to the records in their possession.

148. Plaintiff United States, being unaware of the falsity of the claims caused to be made by Defendants as alleged herein, and in reliance on the accuracy thereof, paid and continue to pay for off-label prescriptions of the Flector Patch.

149. By reason of the conduct described above, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid numerous claims for off-label prescriptions for indications that were not approved by the FDA and/or for prescriptions that were illegally induced by Defendants.

150. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 for each and every violation alleged herein.

COUNT II
FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(B)

151. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

152. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

153. The False Claims Act has been repeatedly violated by Defendants through the fact that their conduct knowingly resulted in claims being made under Medicare, Medicaid, TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and federal workers' compensation programs, which arose out of financial transactions in cash and in kind paid by Defendants in violation of the Anti-Kickback Statute. In turn, such claims were submitted to the Government by Medicare, Medicaid, TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and/or federal workers' compensation programs participating pharmacy benefit providers which those providers had certified as not having violated the Anti-Kickback Statute and/or other federal statutes.

154. The submission of these falsely certified claims was the intended and foreseeable result of Defendants' conduct.

155. By virtue of the above-described acts, among others, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to knowingly make, use or cause to be made or used false records or statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees, or agents of the United States, for the Flector Patch.

156. The amounts of the false or fraudulent claims to the United States were material.

157. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities,

across the United States. Relator has no control over or dealings with such entities and has no access to the records in their possession.

158. Plaintiff United States, being unaware of the falsity of records or statements caused to be made by Defendants, and in reliance on the accuracy thereof paid and continue to erroneously pay for the Flector Patch.

159. By reason of the conduct described above, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid numerous claims for off-label prescriptions for indications that were not approved by the FDA and/or for prescriptions that were illegally induced by Defendants.

160. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 for each and every violation alleged herein.

COUNT III
FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(C)

161. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

162. By the foregoing acts and omissions, Defendants entered into unlawful marketing conspiracies with healthcare providers to defraud the United States by causing false and fraudulent claims to be paid and approved in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

163. By effectuating illegal financial relationships with physicians who do not routinely treat acute pain conditions and other healthcare providers throughout the nation for the purpose of increasing the number of Flector Patch prescriptions written by such healthcare

providers, Defendants and healthcare providers not only violated the Anti-Kickback Statute but conspired to, intended to, and did defraud the United States government by causing the submission of false prescription reimbursement claims for the Flector Patch.

164. Defendants committed overt acts in furtherance of its conspiracies as alleged above, including Defendants' payment of kickbacks.

165. The false or fraudulent claims caused to be submitted to the Government as a direct and proximate result of Defendants' conspiracies were material.

166. Plaintiff United States, being unaware of the falsity of the claims and/or statements caused to be presented by Defendants and their co-conspirators, and in reliance on the accuracy thereof, paid and continues to pay for the Flector Patch.

167. As Defendants' fraudulent practices extend throughout the nation in states where government reimbursement rates make such fraud lucrative for Defendants, and caused the submission of false claims for the Flector Patch pursuant thereto, the amount of total damages to the government amounts to hundreds of millions of dollars, to be proven at trial.

168. The United States *ex rel.* Plaintiff-Relator is entitled to multiple damages under the False Claims Act, to be determined at trial. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 for each and every violation alleged herein.

COUNT IV
CALIFORNIA FALSE CLAIMS ACT
Cal. Gov't Code §12651(a)(1) and (2)

169. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

170. This is a claim for treble damages and penalties under the California False Claims Act.

171. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of California, including the Flector Patch.

172. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of California, for the Flector Patch.

173. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of California, for the Flector Patch.

174. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

175. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of California. Relator has no control over or dealings with such entities and has no access to the records in their possession.

176. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

177. By reason of the Defendants' actions, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

178. Additionally, the California State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT V
CONSPIRACY TO SUBMIT FALSE CLAIMS IN VIOLATION OF THE
CALIFORNIA FALSE CLAIMS ACT
Cal. Gov't Code §12651(a)(3)

179. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

180. As alleged herein, physicians entered into unlawful conspiracies with Defendants pursuant to which, among other things, Defendants paid kickbacks to physicians in exchange for writing off-label prescriptions for the Flector Patch. Defendants and physicians entered into conspiracies willfully and intentionally.

181. By entering the illegal kickback agreement detailed herein, Defendants and physicians conspired to defraud the State of California by causing the submission of false claims for the Flector Patch.

182. As a result of the claims for reimbursement Defendants and physicians caused to be submitted to California Medicaid pursuant to their conspiracies, all of which contained false certifications of compliance with federal and state Medicaid law and regulation as a condition of

reimbursement paid to pharmacy benefit providers for the Flector Patch, California through its Medicaid program regularly made payments to pharmacies for the Flector Patch.

183. The amounts of the false or fraudulent claims to the State of California were material.

184. Plaintiff State of California, being unaware of the falsity of the claims and/or statements caused to be made to Defendants and its co-conspirators, and in reliance on the accuracy thereof paid and continues to pay for the Flector Patch.

COUNT VI
DELAWARE FALSE CLAIMS AND REPORTING ACT
6 Del C. §1201(a)(1) and (2)

185. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

186. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

187. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Delaware, including the Flector Patch.

188. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Delaware, for the Flector Patch.

189. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false

records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Delaware, for the Flector Patch.

190. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

191. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Delaware. Relator has no control over or dealings with such entities and has no access to the records in their possession.

192. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

193. By reason of the Defendants' actions, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

194. Additionally, the Delaware State Government is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT VII
CONSPIRACY TO SUBMIT FALSE CLAIMS IN VIOLATION OF
THE DELAWARE FALSE CLAIMS AND REPORTING ACT
6 Del C. Tit. VI §1201(a)(3)

195. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

196. By entering into illegal kickback agreements as detailed herein, Defendants conspired with healthcare providers to defraud the State of Delaware by causing the submission of false claims for the Flector Patch. At all times relevant to the Complaint, Defendants knowingly violated the Anti-Kickback Statute.

197. As a result of the claims for reimbursement Defendants caused to be submitted to Delaware Medicaid pursuant to their unlawful conspiracy, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to physicians who do not routinely treat acute pain conditions and other healthcare providers, Delaware regularly made payments to pharmacies for the Flector Patch.

198. The amounts of the false or fraudulent claims to the State of Delaware were material.

199. Plaintiff State of Delaware, being unaware of the falsity of the claims and/or statements made by the conspirators, and in reliance on the accuracy thereof paid and continues to pay for the Flector Patch.

COUNT VIII
FLORIDA FALSE CLAIMS ACT
Fla. Stat. Ann. §68.082(2)

200. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

201. This is a claim for treble damages and penalties under the Florida False Claims Act.

202. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Florida, including the Flector Patch.

203. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Florida, for the Flector Patch.

204. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Florida, for the Flector Patch.

205. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

206. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Florida. Relator has no control over or dealings with such entities and has no access to the records in their possession.

207. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid

and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

208. By reason of the Defendants' actions, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

209. Additionally, the Florida State Government is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT IX
CONSPIRACY TO SUBMIT FALSE CLAIMS IN VIOLATION
OF THE FLORIDA FALSE CLAIMS ACT
Fla. Stat. Ann. §68.082(2)(C)

210. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

211. As alleged herein, physicians entered into unlawful conspiracies with Defendants pursuant to which, among other things, Defendants paid kickbacks to physicians in exchange for writing off-label prescriptions for the Flector Patch. Defendants and physicians entered into conspiracies willfully and intentionally.

212. By entering the illegal kickback agreement detailed herein, Defendants and physicians conspired to defraud the State of Florida by causing the submission of false claims for the Flector Patch.

213. As a result of the claims for reimbursement Defendants and physicians caused to be submitted to Florida Medicaid pursuant to their conspiracies, all of which contained false certifications of compliance with federal and state Medicaid law and regulation as a condition of

reimbursement paid to pharmacy benefit providers for the Flector Patch, Florida through its Medicaid program regularly made payments to pharmacies for the Flector Patch.

214. The amounts of the false or fraudulent claims to the State of Florida were material.

215. Plaintiff State of Florida, being unaware of the falsity of the claims and/or statements caused to be made to Defendants and its co-conspirators, and in reliance on the accuracy thereof paid and continues to pay for the Flector Patch.

COUNT X
GEORGIA FALSE MEDICAID CLAIMS ACT
Ga. Code Ann. §49-4-168.1(1) and (2)

216. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

217. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

218. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Georgia, including the Flector Patch.

219. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Georgia, for the Flector Patch.

220. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false

records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Georgia, for the Flector Patch.

221. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

222. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Georgia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

223. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

224. By reason of the Defendants' actions, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

225. Additionally, the Georgia State Government is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XI
HAWAII FALSE CLAIMS ACT
Haw. Rev. Stat. §661-21(a)

226. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

227. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

228. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Hawaii, including the Flector Patch.

229. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Hawaii, for the Flector Patch.

230. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Hawaii, for the Flector Patch.

231. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

232. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous

separate entities across the State of Hawaii. Relator has no control over or dealings with such entities and has no access to the records in their possession.

233. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

234. By reason of the Defendants' actions, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

235. Additionally, the Hawaii State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XII
ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT
740 Ill. Comp. Stat. §175/3(a)(1) and (2)

236. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

237. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward and Protection Act.

238. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Illinois, including the Flector Patch.

239. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or

approval, directly or indirectly, to officers, employees or agents of the State of Illinois, for the Flector Patch.

240. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Illinois, for the Flector Patch.

241. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

242. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Illinois. Relator has no control over or dealings with such entities and has no access to the records in their possession.

243. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

244. By reason of the Defendants' actions, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

245. Additionally, the Illinois State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XIII
CONSPIRACY TO SUBMIT FALSE CLAIMS IN VIOLATION OF
THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT
740 Ill. Comp. Stat. §175/3(a)(3)

246. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

247. By entering into illegal kickback agreements as detailed herein, Defendants conspired with healthcare providers to defraud the State of Illinois by causing the submission of false claims for the Flector Patch. At all times relevant to the Complaint, Defendants knowingly violated the Anti-Kickback Statute.

248. As a result of the claims for reimbursement Defendants caused to be submitted to Illinois Medicaid pursuant to their unlawful conspiracy, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to physicians who do not routinely treat acute pain conditions and other healthcare providers, Illinois regularly made payments to pharmacies for the Flector Patch.

249. The amounts of the false or fraudulent claims to the State of Illinois were material.

250. Plaintiff State of Illinois, being unaware of the falsity of the claims and/or statements made by the conspirators, and in reliance on the accuracy thereof paid and continues to pay for the Flector Patch.

COUNT XIV
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT
Ind. Code Ann. §5-11-5.5-2(b)(1) and (2)

251. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

252. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

253. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Indiana, including the Flector Patch.

254. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Indiana, for the Flector Patch.

255. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Indiana, for the Flector Patch.

256. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

257. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Indiana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

258. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

259. By reason of the Defendants' actions, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

260. Additionally, the Indiana State Government is entitled to the maximum penalty of \$5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XV
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
La. Rev. Stat. §437 et seq.

261. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

262. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

263. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Louisiana, including the Flector Patch.

264. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and

continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Louisiana, for the Flector Patch.

265. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Louisiana, for the Flector Patch.

266. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

267. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Louisiana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

268. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

269. By reason of the Defendants' actions, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

270. Additionally, the Louisiana State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XVI
MASSACHUSETTS FALSE CLAIMS LAW
Mass. Gen. Laws ch. 12 §5B(1) and (2)

271. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

272. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

273. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Massachusetts, including the Flector Patch.

274. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Massachusetts, for the Flector Patch.

275. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Massachusetts, for the Flector Patch.

276. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

277. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Massachusetts. Relator has no control over or dealings with such entities and has no access to the records in their possession.

278. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

279. By reason of the Defendants' actions, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

280. Additionally, the Massachusetts State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XVII
MICHIGAN MEDICAID FALSE CLAIMS ACT
Mich. Comp. Laws. §400.601 et seq.

281. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

282. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

283. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Michigan, including the Flector Patch.

284. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Michigan, for the Flector Patch.

285. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Michigan, for the Flector Patch.

286. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

287. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Michigan. Relator has no control over or dealings with such entities and has no access to the records in their possession.

288. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid

and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

289. By reason of the Defendants' actions, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

290. Additionally, the Michigan State Government is entitled to the maximum civil penalties for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XVIII
MONTANA FALSE CLAIMS ACT
Mont. Code Ann. §17-8-403(1)(a) and (b)

291. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

292. This is a claim for treble damages and penalties under the Montana False Claims Act.

293. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Montana, including the Flector Patch.

294. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Montana, for the Flector Patch.

295. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false

records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Montana, for the Flector Patch.

296. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

297. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Montana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

298. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

299. By reason of the Defendants' actions, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

300. Additionally, the Montana State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XIX
NEVADA FALSE CLAIMS ACT
Nev. Rev. Stat. Ann. §357.040(1)(a) and (b)

301. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

302. This is a claim for treble damages and penalties under the Nevada False Claims Act.

303. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Nevada, including the Flector Patch.

304. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Nevada, for the Flector Patch.

305. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Nevada, for the Flector Patch.

306. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

307. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous

separate entities across the State of Nevada. Relator has no control over or dealings with such entities and has no access to the records in their possession.

308. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

309. By reason of the Defendants' actions, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

310. Additionally, the Nevada State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XX
NEW HAMPSHIRE FALSE CLAIMS ACT
N.H. Rev. Stat. Ann. §167:61-b(I)(a) and (b)

311. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

312. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

313. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of New Hampshire, including the Flector Patch.

314. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or

approval, directly or indirectly, to officers, employees or agents of the State of New Hampshire, for the Flector Patch.

315. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of New Hampshire, for the Flector Patch.

316. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

317. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of New Hampshire. Relator has no control over or dealings with such entities and has no access to the records in their possession.

318. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

319. By reason of the Defendants' actions, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

320. Additionally, the New Hampshire State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXI
CONSPIRACY TO SUBMIT FALSE CLAIMS IN VIOLATION OF
THE NEW HAMPSHIRE FALSE CLAIMS ACT

321. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

322. By entering into illegal kickback agreements as detailed herein, Defendants conspired with healthcare providers to defraud the State of New Hampshire by causing the submission of false claims for the Flector Patch. At all times relevant to the Complaint, Defendants knowingly violated the Anti-Kickback Statute.

323. As a result of the claims for reimbursement Defendants caused to be submitted to New Hampshire Medicaid pursuant to their unlawful conspiracy, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to physicians who do not routinely treat acute pain conditions and other healthcare providers, New Hampshire regularly made payments to pharmacies for the Flector Patch.

324. The amounts of the false or fraudulent claims to the State of New Hampshire were material.

325. Plaintiff State of New Hampshire, being unaware of the falsity of the claims and/or statements made by the conspirators, and in reliance on the accuracy thereof paid and continues to pay for the Flector Patch.

COUNT XXII
NEW JERSEY FALSE CLAIMS ACT
N.J. Stat. § 2A:32C-1, et seq.

326. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

327. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

328. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of New Jersey, including the Flector Patch.

329. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of New Jersey, for the Flector Patch.

330. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of New Jersey, for the Flector Patch.

331. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

332. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous

separate entities across the State of New Jersey. Relator has no control over or dealings with such entities and has no access to the records in their possession.

333. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

334. By reason of the Defendants' actions, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

335. Additionally, the New Jersey State Government is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXIII
NEW MEXICO MEDICAID FALSE CLAIMS ACT
N.M. Stat. Ann. §27-14-4

336. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

337. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

338. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of New Mexico, including the Flector Patch.

339. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or

approval, directly or indirectly, to officers, employees or agents of the State of New Mexico, for the Flector Patch.

340. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of New Mexico, for the Flector Patch.

341. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

342. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of New Mexico. Relator has no control over or dealings with such entities and has no access to the records in their possession.

343. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

344. By reason of the Defendants' actions, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

345. Additionally, the New Mexico State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXIV
NEW YORK FALSE CLAIMS ACT
N.Y. State Fin. §189(1)(A) and (B)

346. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

347. This is a claim for treble damages and penalties under the New York False Claims Act.

348. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of New York, including the Flector Patch.

349. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of New York, for the Flector Patch.

350. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of New York, for the Flector Patch.

351. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

352. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of New York. Relator has no control over or dealings with such entities and has no access to the records in their possession.

353. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

354. By reason of the Defendants' actions, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

355. Additionally, the New York State Government is entitled to the maximum penalty of \$12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXV
CONSPIRACY TO SUBMIT FALSE CLAIMS IN VIOLATION OF
NEW YORK FALSE CLAIMS ACT

356. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

357. By entering into illegal kickback agreements as detailed herein, Defendants conspired with healthcare providers to defraud the State of New York by causing the submission

of false claims for the Flector Patch. At all times relevant to the Complaint, Defendants knowingly violated the Anti-Kickback Statute.

358. As a result of the claims for reimbursement Defendants caused to be submitted to New York Medicaid pursuant to their unlawful conspiracy, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to physicians who do not routinely treat acute pain conditions and other healthcare providers, New York regularly made payments to pharmacies for the Flector Patch.

359. The amounts of the false or fraudulent claims to the State of New York were material.

360. Plaintiff State of New York, being unaware of the falsity of the claims and/or statements made by the conspirators, and in reliance on the accuracy thereof paid and continues to pay for the Flector Patch.

COUNT XXVI
OKLAHOMA MEDICAID FALSE CLAIMS ACT
Okla. Stat. tit. 63 §5053.1(B)(1) and (2)

361. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

362. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

363. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Oklahoma, including the Flector Patch.

364. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or

approval, directly or indirectly, to officers, employees or agents of the State of Oklahoma, for the Flector Patch.

365. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Oklahoma, for the Flector Patch.

366. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

367. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Oklahoma. Relator has no control over or dealings with such entities and has no access to the records in their possession.

368. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

369. By reason of the Defendants' actions, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

370. Additionally, the Oklahoma State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXVII
RHODE ISLAND FALSE CLAIMS ACT
R.I. Gen. Laws §9-1.1-3(a)(1), (2) and (7)

371. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

372. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

373. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Rhode Island, including the Flector Patch.

374. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Rhode Island, for the Flector Patch.

375. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Rhode Island, for the Flector Patch.

376. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

377. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Rhode Island. Relator has no control over or dealings with such entities and has no access to the records in their possession.

378. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

379. By reason of the Defendants' actions, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

380. Additionally, the Rhode Island State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXVIII
TENNESSEE FALSE CLAIMS ACT AND TENNESSEE MEDICAID FALSE CLAIMS
ACT
Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(1)

381. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

382. This is a claim for treble damages and penalties under the Tennessee False Claims Act and Tennessee Medicaid False Claims Act.

383. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Tennessee, including the Flector Patch.

384. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Tennessee, for the Flector Patch.

385. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Tennessee, for the Flector Patch.

386. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

387. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Tennessee. Relator has no control over or dealings with such entities and has no access to the records in their possession.

388. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

389. By reason of the Defendants' actions, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

390. Additionally, the Tennessee State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXIX
CONSPIRACY TO SUBMIT FALSE CLAIMS IN VIOLATION OF
THE TENNESSEE MEDICAID FALSE CLAIMS ACT
Tenn. Code Ann. § 71-5-182(c)

391. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

392. By entering into illegal kickback agreements as detailed herein, Defendants conspired with healthcare providers to defraud the State of Tennessee by causing the submission of false claims for the Flector Patch. At all times relevant to the Complaint, Defendants knowingly violated the Anti-Kickback Statute.

393. As a result of the claims for reimbursement Defendants caused to be submitted to Tennessee Medicaid pursuant to their unlawful conspiracy, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to physicians who do not routinely treat acute pain conditions and other healthcare providers, Tennessee regularly made payments to pharmacies for the Flector Patch.

394. The amounts of the false or fraudulent claims to the State of Tennessee were material.

395. Plaintiff State of Tennessee, being unaware of the falsity of the claims and/or statements made by the conspirators, and in reliance on the accuracy thereof paid and continues to pay for the Flector Patch.

COUNT XXX
TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code Ann. §36.002

396. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

397. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

398. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Texas, including the Flector Patch.

399. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Texas, for the Flector Patch.

400. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or

approved, directly or indirectly, by officers, employees or agents of the State of Texas, for the Flector Patch.

401. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

402. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Texas. Relator has no control over or dealings with such entities and has no access to the records in their possession.

403. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

404. By reason of the Defendants' actions, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

405. Additionally, the Texas State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXXI
CONSPIRACY TO SUBMIT FALSE CLAIMS IN VIOLATION OF
THE TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code Ann. §36.002(9)

406. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

407. By entering into illegal kickback agreements as detailed herein, Defendants conspired with healthcare providers to defraud the State of Texas by causing the submission of false claims for the Flector Patch. At all times relevant to the Complaint, Defendants knowingly violated the Anti-Kickback Statute.

408. As a result of the claims for reimbursement Defendants caused to be submitted to Texas Medicaid pursuant to their unlawful conspiracy, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to physicians who do not routinely treat acute pain conditions and other healthcare providers, Texas regularly made payments to pharmacies for the Flector Patch.

409. The amounts of the false or fraudulent claims to the State of Texas were material.

410. Plaintiff State of Texas, being unaware of the falsity of the claims and/or statements made by the conspirators, and in reliance on the accuracy thereof paid and continues to pay for the Flector Patch.

COUNT XXXII
VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. §8.01-216.3(a)(1) and (2)

411. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

412. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

413. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Virginia, including the Flector Patch.

414. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Virginia, for the Flector Patch.

415. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Virginia, for the Flector Patch.

416. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

417. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Virginia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

418. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

419. By reason of the Defendants' actions, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

420. Additionally, the Virginia State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXXIII
CONSPIRACY TO SUBMIT FALSE CLAIMS IN VIOLATION OF
THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. §8.01-216.3(3)

421. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

422. By entering into illegal kickback agreements as detailed herein, Defendants conspired with healthcare providers to defraud the State of Virginia by causing the submission of false claims for the Flector Patch. At all times relevant to the Complaint, Defendants knowingly violated the Anti-Kickback Statute.

423. As a result of the claims for reimbursement Defendants caused to be submitted to Virginia Medicaid pursuant to their unlawful conspiracy, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to physicians who do not routinely treat acute pain conditions and other healthcare providers, Virginia regularly made payments to pharmacies for the Flector Patch.

424. The amounts of the false or fraudulent claims to the State of Virginia were material.

425. Plaintiff State of Virginia, being unaware of the falsity of the claims and/or statements made by the conspirators, and in reliance on the accuracy thereof paid and continues to pay for the Flector Patch.

COUNT XXXIV
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT
Wis. Stat §20.931(2)(a), (b) and (g)

426. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

427. This is a claim for treble damages and penalties under the Wisconsin False Claims for Medical Assistance Act.

428. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the State of Wisconsin, including the Flector Patch.

429. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Wisconsin, for the Flector Patch.

430. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the State of Wisconsin, for the Flector Patch.

431. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

432. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the State of Wisconsin. Relator has no control over or dealings with such entities and has no access to the records in their possession.

433. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

434. By reason of the Defendants' actions, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

435. Additionally, the Wisconsin State Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXXV
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT,
D.C. Code Ann. § 1-1188.13 et seq.

436. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

437. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

438. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, pharmaceuticals in the District of Columbia, including the Flector Patch.

439. By virtue of the acts described above, among others, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval, and continue knowingly to present or cause to be presented false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the District of Columbia, for the Flector Patch.

440. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid or approved, and continue to make, use, or cause to be made or used false records and statements, and omit material facts, to get false or fraudulent claims paid or approved, directly or indirectly, by officers, employees or agents of the District of Columbia, for the Flector Patch.

441. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a state-funded health insurance program represents a false or fraudulent claim for payment.

442. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented by numerous separate entities across the District of Columbia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

443. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for the Defendants' illegal off-label marketing practices and/or illegal inducements.

444. By reason of the Defendants' actions, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

445. Additionally, the District of Columbia Government is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

PRAYER

WHEREFORE, Relator prays for judgment against Defendants as follows:

1. that Defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the counterpart provisions of the States and the District of Columbia statutes set forth above;
2. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of the actions of Defendants, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. §3729;
3. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Cal. Govt. Code §12651(a);
4. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of the actions of Defendants, plus a civil penalty of \$11,000 for each violation of 6 Del. C. §1201(a);

5. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of the actions of Defendants, plus a civil penalty of \$11,000 for each violation of Fla. Stat. Ann. §68.082(2);

6. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of the actions of Defendants, plus a civil penalty of \$11,000 for each violation of Ga. Code Ann. §49-4-168.1;

7. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Haw. Rev. Stat. §661-21(a);

8. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

9. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of the actions of Defendants, plus a civil penalty of \$5,000 for each violation of Ind. Code Ann. §5-11-5.5-2(b);

10. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of La. Rev. Stat. §437 et seq.;

11. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

12. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of the actions of Defendants, plus civil penalties for each violation of Mich. Comp. Laws. §400.601 et seq.;

13. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Mont. Code Ann. §17-8-401;

14. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

15. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of N.H. Rev. Stat. Ann. §167.61-b(1);

16. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of the actions of Defendants, plus a civil penalty of \$11,000 for each violation of N.J. Stat. § 2A:32C-1, et seq.;

17. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of N.M. Stat. Ann. §27-2F-4;

18. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of the actions of Defendants, plus a civil penalty of \$12,000 for each violation of N.Y. State Fin. §189(1);

19. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Okla. Stat. tit. 63 §5053.1(B);

20. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of R.I. Gen. Laws §9-1.1-3(a);

21. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(1);

22. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

23. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Va. Code Ann. §8.01-216.3(a);

24. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of Wis. Stat §20.931(2);

25. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of the actions of Defendants, plus a civil penalty of \$10,000 for each violation of D.C. Code Ann. §2-308.14(a);

26. that Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

27. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

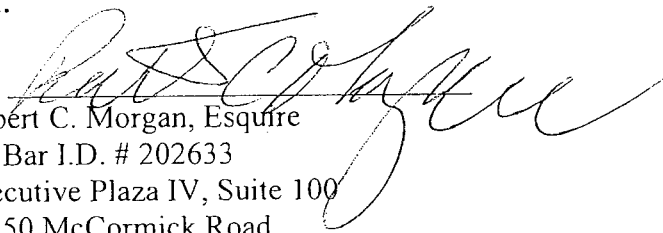
28. that Relator recover such other relief as the Court deems just and proper, or that is necessary to make Relator whole.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

**MORGAN CARLO DOWNS & EVERTON,
P.A.**

Dated: April 20, 2010

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